

## REMARKS:

Applicant has carefully studied the Final Examiner's Action and all references cited therein. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings that correspond to the centered headings employed by the Office, to ensure full response on the merits to each finding of the Office.

### **Claim Objections**

Claims 3 and 4 stand objected to due to informalities.

Claims 3 and 4 have been amended to objection the objections by the Office and are now believed to be in condition for allowance.

### **Claim Rejections – 35 U.S.C. § 102**

Applicant acknowledges the quotation of 35 U.S.C § 102(b).

Claims 1-8, 10 and 19-28 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,318,514 to Hofmann.

With respect to claim 1, the Office states that Hofmann discloses a device for electromanipulation of chemical species in vivo relative to a target tissue (abstract) comprising: a substantially planar nonconductive (col. 2, lines 39-44) sheet (22) conformable (via pins 28) to the surface of the target tissue (column 2, lines 61-63); a plurality of electrode elements (18) secured in spaced apart relation on the array base (figures 2 and 3), the electrode elements adapted to be coupled to an electrical source (column 2, lines 49-50).

Independent claim 1 has been amended to more clearly describe that which Applicant regards as the invention.

Amended claim 1 describes, a device for electromanipulation of chemical species in vivo relative to a target tissue comprising: a voltage controlled and current controlled electrical source; a substantially planar nonconductive sheet conformable to the three-dimensional topography of the surface of the target tissue; and a plurality of electrode elements secured in spaced apart relation on the sheet, the electrode elements coupled to receive a voltage controlled and current controlled output from the electrical source and the electrode elements being spaced together in sufficient proximity to insure that a peak power of less than 1 kilowatt is needed for electromanipulation of the target tissue.

Support for the amendment to the claims can be found in the specification as originally filed. For example, support for the voltage controlled and current controlled electrical source can be found at paragraph [0048]. Accordingly, no new matter has been added.

As such, amended claim 1 includes the additional limitations of: (1) a substantially planar nonconductive sheet that is conformable to the three-dimensional topography of the surface of the target tissue, (2) a voltage controlled and current controlled electrical source, and (3) the spacing of the electrode elements in combination with the voltage controlled and current controlled source such that a peak power of less than 1 kilowatt is needed for electromanipulation of the target tissue.

Applicant contends that Hofmann does not anticipate amended claim 1 because Hoffman does not teach: (1) a substantially planar nonconductive sheet that is conformable to the three-dimensional topography of the surface of the target tissue, (2) a voltage controlled and current controlled electrical source, and (3) the spacing of the electrode elements in combination with the voltage controlled and current controlled source such that a peak power of less than 1 kilowatt is needed for electromanipulation of the target tissue.

For the reasons indicated above, amended independent claim 1 is not anticipated by Hofmann and is believed to be in condition for allowance.

Claims 3-8, 10-11 and 14-22 are dependent upon claim 1, which has been shown to be allowable, and are therefore allowable as a matter of law.

Claim 9 has been cancelled.

With respect to claim 23, the Office states that Hofmann discloses a device for electromanipulation of chemical species in vivo relative to a target tissue (abstract) comprising: a substantially planar nonconductive (col. 2, lines 39-44) sheet (22) conformable (via pins 28) to the surface of the target tissue (column 2, lines 61-63); a plurality of electrode elements (18) projecting from sheet towards the target tissue (figure 3); the electrode elements individually addressable, plurality of electrodes adapted to be coupled to an electrical source (column 2, lines 49-50); a control means interposed between the electrical source and the plurality of electrode elements and in circuit communication therein (12), the control means adapted to establish an electrical potential between at least two electrodes; and a delivery means adapted to introduce chemical species to the target tissue (col. 3, lines 33-41).

Independent claim 23 has been amended to more clearly describe that which Applicant regards as the invention.

Amended claim 23 describes, a device for manipulation of chemical species in vivo relative to a target tissue comprising: a voltage controlled and current controlled electrical source; a substantially planar nonconductive sheet conformable to the topography of the three-dimensional surface of the target tissue; a plurality of electrode elements projecting from the sheet towards the target tissue, the electrode elements addressable individually, the plurality of electrodes coupled to receive a voltage controlled and current controlled output from the electrical source and wherein the plurality of electrode elements are spaced together in sufficient proximity to insure that an electrical power having a peak of less than 1 kilowatt is needed for electromanipulation of the target tissue; a control means interposed between the electrical source and the plurality of electrode elements and in circuit communication therein, the control means adapted to establish the electrical potential between at least two electrodes of the plurality of electrodes; and a delivery means adapted to introduce chemical species to the target tissue.

Support for the amendment to the claims can be found in the specification as originally filed. For example, support for the voltage controlled and current controlled electrical source can be found at paragraph [0048]. Accordingly, no new matter has been added.

As such, amended claim 23 includes the additional limitations of: (1) a substantially planar nonconductive sheet that is conformable to the three-dimensional topography of the surface of the target tissue, (2) a voltage controlled and current controlled electrical source, and (3) the spacing of the electrode elements in combination with the voltage controlled and current controlled source such that a peak power of less than 1 kilowatt is needed for electromanipulation of the target tissue.

Applicant contends that Hofmann does not anticipate amended claim 23 because Hoffman does not teach: (1) a substantially planar nonconductive sheet that is conformable to the three-dimensional topography of the surface of the target tissue, (2) a voltage controlled and current controlled electrical source, and (3) the spacing of the electrode elements in combination with the voltage controlled and current controlled source such that a peak power of less than 1 kilowatt is needed for electromanipulation of the target tissue.

For the reasons indicated above, amended independent claim 23 is not anticipated by Hofmann and is believed to be in condition for allowance.

Regarding independent claim 24, the Office states that Hofman discloses a method for electromanipulation of chemical species in vivo relative to a target tissue comprising the steps of: placing at least one substantially planar nonconductive sheet (22) conformable to the topography of the surface of the target tissue coincident to the target tissue (col. 2, lines 61-62), the at least one sheet (22) containing a plurality of electrode elements (18), (column 3, lines 5-8); establishing an electrical potential between at least two electrode elements in the plurality of electrode elements; providing a chemical species coincident to the target tissue (col. 3, lines 4-5); controlling the electrical potential whereby the chemical species are delivered to the target tissue (col. 3, lines 9-19, lines 33-41).

Claim 24 has been amended to more clearly describe that which the Applicant regards as the invention.

Amended claim 24 describes a method for electromanipulation of chemical species in vivo relative to a target tissue comprising the steps of: placing at least one substantially planar nonconductive sheet conformable to the three-dimensional topography of the surface of the target tissue coincident to the target tissue, the at least one sheet containing a plurality of electrode elements; establishing an electrical potential between at least two electrode elements in the plurality of electrode elements, the electrical potential having a set voltage level and set current level such that the electrical power delivered to the at least two electrodes is less than about 1kW; providing a chemical species coincident to the target tissue; and controlling the electrical potential whereby the chemical species are delivered to the target tissue.

Applicant contends that Hofmann does not anticipate claim 24 because Hofmann does not describe: (1) placing at least one substantially planar nonconductive sheet conformable to the three-dimensional topography of the surface of the target tissue coincident to the target tissue, the at least one sheet containing a plurality of electrode elements, and (2) establishing an electrical potential between at least two electrode elements in the plurality of electrode elements, the electrical potential having a set voltage level and set current level such that the electrical power delivered to the at least two electrodes is less than about 1kW.

For the reasons indicated above, amended claim 24 of the present invention is not anticipated by Hofmann and is believed to be in condition for allowance.

Claims 25-29 are dependent upon claim 24, which has been shown to be allowable, and are therefore allowable as a matter of law.

### **Claim Rejections – 35 U.S.C. § 103**

Applicant acknowledges the quotation of 35 U.S.C § 103(a).

Claims 9 and 11 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,318,514 to Hofmann.

With respect to claim 9, the Office states that Hofmann discloses the device of claim 1 except wherein the electrode elements are spaced together in sufficient proximity to insure that a peak power of less than 1 kilowatt is needed to electromanipulation of the target tissue. More specifically, the Office states that Hofmann teaches using a low voltage (with a field strength from about 0.2kV/cm to about 20kV/cm) in claim 1, however Hofmann is silent to the spacing of the electrode elements. The Office concludes that it would have been obvious to one having ordinary skill in the art at the time the invention was made to arrange the electrode elements in order to achieve the desired output from the electromanipulation device.

Claim 9 has been cancelled by amendment and the elements of claim 9 have been incorporated into independent claim 1, 23 and 24. As such, Applicant provides an argument that previous claim 9 is patentable over Hofmann.

Applicant respectfully disagrees with the finding by the Office that claim 9 is unpatentable in view of Hofmann. While Hofmann teaches using a low voltage source, with a field strength from about 0.2kV/cm to about 20kV/cm, and it is known in the art to adjust the spacing between the electrodes to achieve a particular electrical field between the electrodes, Applicant contends that such an arrangement would not result in a peak power of less than 1 kilowatt as claimed by the present invention.

Electrical power is known in the art to be a combination of both the electric field between the electrodes and the current applied. While Hofmann suggests applying a low voltage source to the electrodes, Hofmann does not teach or suggest controlling the resulting current. It is known in the art to set the voltage supply to provide a certain voltage potential to the electrodes, and to then let the power supply deliver whatever current is necessary to provide the desired electric field. Controlling the applied voltage does not control the power level if the current is not controlled. Additionally, adjusting the spacing between the electrodes does not control the power level either, because adjusting the spacing effects the electric field between the electrodes, but not the current from the power supply.

For the reasons indicated above, Applicant contends that previous claim 9 (now incorporated into independent claim 1, 23 and 24) is patentable over Hofmann.

If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (813) 925-8505 is requested.

Very respectfully,  
SMITH & HOPEN

/molly sauter/

Dated: October 28, 2008

Customer No. 21,901

By: \_\_\_\_\_  
Molly L. Sauter  
180 Pine Avenue North  
Oldsmar, Florida 34677  
Agent for Applicant  
Reg No. 46,457

**CERTIFICATE OF ELECTRONIC TRANSMISSION**

**(37 C.F.R. 2.190 (b))**

I HEREBY CERTIFY that this Preliminary Amendment is being electronically transmitted to the Patent and Trademark Office through EFS Web on October 28, 2008.

Date: October 28, 2008

/erica gossage/

\_\_\_\_\_  
Erica Gossage